UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2738
This Document Relates To All Cases	

DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' STEERING COMMITTEE'S MOTION TO EXCLUDE THE OPINIONS OF DEFENDANTS' EXPERTS BROOKE T. MOSSMAN, M.S., PH.D., KELLY S. TUTTLE, PH.D., AND H. NADIA MOORE, PH.D.

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Plaintiffs' motion purports to request that the Court fully exclude the opinions of defendants' experts Brooke T. Mossman, M.S., Ph.D.; Kelly S. Tuttle, Ph.D. and H. Nadia Moore, Ph.D., but they do not attack the core of these experts' opinions – specifically: (1) Dr. Mossman's primary opinion that nonasbestos cleavage fragments do not pose the health risks to humans that may be posed by asbestos; and (2) Drs. Tuttle and Moore's various opinions related to heavy metals and fragrances, including their fundamental critiques of plaintiffs' experts' failure to consider dose in assessing the purported health risks posed by those metals and ingredients, as well as their ultimate conclusions that none of the heavy metals or fragrance ingredients listed by plaintiffs' experts has been shown to cause ovarian cancer. These are the cornerstones of the experts' reports, and plaintiffs' failure to challenge them effectively concedes their admissibility.

To the extent plaintiffs' motion does address these experts' other opinions, plaintiffs fundamentally distort what the experts wrote in their reports and said in their depositions; grossly minimize the relevant expertise of the experts at issue; and repeatedly assert that the experts failed to consider various evidence that is either irrelevant to the challenged opinions, unsupportive of plaintiffs' theories of causation, or both. For these reasons, discussed further below, plaintiffs do not offer a single legitimate reason why any of the three experts' opinions should be excluded, even in part.

BACKGROUND

A. Brooke T. Mossman, M.S., PH.D.

Dr. Brooke Mossman is a leader in the field of fiber carcinogenesis and asbestos-related disease. She has more than 40 years of research experience, and her specialties include environmental toxicology, mesothelial and epithelial cell differentiation, chemical and physical carcinogenesis and cell injury, pulmonary fibrosis, reactive oxygen species, molecular biology of antioxidant enzymes and cell signaling pathways leading to inflammation and cancer.[1] In her current role as Emeritus and Distinguished Professor of Pathology at the University of Vermont College of Medicine, Dr. Mossman's research focuses on the role of asbestos fibers in the induction of lung cancers, asbestosis and mesotheliomas.[2] In 2017, Dr. Mossman was elected as a Fellow to the Vermont Academy of Arts and Sciences in recognition of her "ground-breaking and award-winning research on mesothelioma and other asbestos-induced diseases."[3] Dr. Mossman's extensive scholarship in the field of fiber carcinogenesis and asbestos-induced cancers is reflected in her publication of 300 refereed papers, books, book chapters, reviews,

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1 (Expert Report of Brooke Taylor Mossman, M.S., Ph.D. ("Mossman Rep.") at 3, Feb. 25, 2019 (attached as Ex. C11 to the Omnibus Certification of Julie L. Tersigni ("Tersigni Cert."), May 7, 2019 (ECF No. 9723-2)).)

2 (*Id.*)

3 (Curriculum Vitae of Brooke Taylor Mossman, M.S., Ph.D. ("Mossman CV") at 1 (Mossman Rep. Ex. C) (citation omitted).)

and monographs on the topics.[4] In addition to performing original research, Dr. Mossman is on the editorial boards of numerous journals, including the American Journal of Respiratory Cell and Molecular Biology, and has been a reviewer for more than 40 journals, including high-impact publications such as the *New England Journal of Medicine*, *Journal of the National Cancer Institute*, *Nature*, *Science* and *Cancer Research*.[5] Dr. Mossman has also served on scientific advisory boards and study sections of the National Heart, Lung and Blood Institute, National Cancer Institute, American Cancer Society, National Institute of Environmental Health Sciences and Environmental Protection Agency.[6]

The core of Dr. Mossman's opinions is that cosmetic talc particles and nonasbestos cleavage fragments have different biological effects from amphibole asbestos due to major chemical, physical and structural differences between the substances. As Dr. Mossman explains, properties such as fiber dimension (long v. short), fiber shape (straight, rod-like vs. tangled/helical), fiber chemistry, flexibility, crystal structure and durability can influence the toxicity and carcinogenicity of a substance.[7] She further opines that dose is also critical to determining whether a

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4 (Mossman Rep. at 3.)

5 (Mossman CV at 2-3.)

6 (Mossman Rep. at 3.)

7 (*See id.* at 15-17.)

substance has carcinogenetic effects.[8] Unlike asbestos, Dr. Mossman explains, talc particles have a distinct crystalline and chemical structure, tend to be plate-like and do not carry a positive charge.[9] Further, Dr. Mossman states that nonasbestos cleavage fragments are blunt, thick fragments and do not break in a parallel fashion to create the long, thin fibers that are characteristic of asbestos.[10] According to Dr. Mossman, both talc and nonasbestos cleavage fragments are cleared out of the lung and female reproductive tract by the body's natural defense mechanisms against foreign particles, which is at odds with plaintiffs' migration theory of biological plausibility.[11]

Dr. Mossman also provides a comprehensive overview of existing literature demonstrating how talc and nonasbestos cleavage fragments do not elicit the same biological responses as asbestos. Dr. Mossman explains that human and animal studies have not provided any evidence linking talc and nonasbestos cleavage fragments to mesothelioma or ovarian cancer development.[12] She also explains

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8 (*See* Dep. of Brooke T. Mossman, M.S., Ph.D. ("Mossman Dep.") 36:18-21, Apr. 8, 2019 (attached as Ex. B7 to Tersigni Cert.).)

9 (*See* Mossman Rep. at 23.)

10 (*Id.* at 19-20.)

11 (*Id.* at 8, 10.)

12 (*Id.* at 21, 23.)

that in vitro studies do not support a link between talc and nonasbestos cleavage fragments and an oxidative stress, inflammation or cancer induction response.[13]

The final component of Dr. Mossman's report is an evaluation of the opinions of plaintiffs' experts, Drs. Saed and Zelikoff. With respect to Dr. Saed, Dr. Mossman identifies several unsupported claims and misrepresentations of scientific publications that appear in Dr. Saed's report and highlights the serious concerns of scientific integrity raised by Dr. Saed's misrepresentation of experimental data, manipulation of lab notebooks and lack of adequate financial disclosure during the peer-review process.[14] As to Dr. Zelikoff, Dr. Mossman addresses her flawed understanding of fundamental concepts of minerology that are critical to understanding the differences between talc and asbestos. Dr. Mossman also addresses the inadequacy of Dr. Zelikoff's literature research, which ignores several high-impact, peer-reviewed publications on talc and ovarian cancer and relies disproportionately on non-peer-reviewed and non-scientific materials. Dr. Mossman also points out how Dr. Zelikoff's plagiarism from the internet and other reports written by plaintiffs' other experts undermine the reliability of her opinions.[15]

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13 (*Id.* at 21-22.)

14 (*See id.* at 28-34.)

15 (*See id.* at 34-43.)

B. Kelly S. Tuttle, Ph.D.

Dr. Kelly Tuttle is a Senior Toxicologist at the Center for Toxicology and Environmental Health, LLC ("CTEH"), with active involvement in the areas of toxicology, human health risk assessment and emergency response.[16] Dr. Tuttle received her Ph.D. in Toxicology from Texas A&M University,[17] and is a Certified Industrial Hygienist ("CIH") through the American Board of Industrial Hygiene.[18] In her current role with CTEH, Dr. Tuttle is active in the area of human and environmental toxicology and has been involved in numerous projects involving the assessment of chemical exposures and their effects on humans.[19] Dr. Tuttle is a member of several organizations within her field, including the Society of Toxicology, the Lone Star Chapter of the Society of Toxicology, the American Conference of Governmental Industrial Hygienists, and the American Industrial Hygiene Association.[20] She has written numerous peer-reviewed publications and grants in toxicology and related fields.[21]

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16 (Expert Report of Kelly Scribner Tuttle, Ph.D., CIH ("Tuttle Rep.") at 1, Feb. 25, 2019 (attached as C26 to Tersigni Cert.).)

17 (*Id.* at 1.)

18 (Curriculum Vitae of Kelly Scribner Tuttle, Ph.D., CIH at 1 (Tuttle Rep. Ex. B).)

19 (Tuttle Rep. at 1.)

20 (*Id.*)

21 (*Id.*)

Dr. Tuttle's report focuses on her two primary opinions that: (1) the scientific literature does not support an association between any of the heavy metals plaintiffs' experts claim are present in Johnson's Baby Powder and/or Shower to Shower ("the Products") and ovarian cancer, and (2) none of the fragrances listed by plaintiffs' experts has been associated with ovarian cancer, and none are present in the Products at levels that are capable of posing any human health concern at all.[22] These opinions are based on Dr. Tuttle's review of the scientific literature and her application of fundamental toxicology principles, including the requirements of both hazard and dose.[23]

Dr. Tuttle's conclusion that none of the heavy metals listed by plaintiffs' experts is causally associated with ovarian cancer is based on an assessment of the scientific literature. Dr. Tuttle performed literature searches to identify any mechanistic or epidemiologic studies linking the six metals cited by plaintiffs (chromium, nickel, cobalt, lead, cadmium and arsenic) to ovarian cancer.[24] She also researched non-occupational exposures to each of those heavy metals in daily life, as well as studies assessing the concentration of heavy metals in talc and talc-containing products.[25] Dr. Tuttle concludes that the concentrations of the heavy

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22 (*See, e.g.*, Tuttle Rep. at 45, 53; *see also id.* at 37-44, 46-53.)

23 (*Id.*)

24 (*Id.* at 37-42.)

25 (*Id.* at 42-44.)

metals in various talc products provided by Imerys and the J&J defendants that were listed in the expert reports of plaintiffs' experts Dr. Mark Krekeler and Dr. Robert Cook are well below the screening levels established for dermal exposures for those metals by the United States Environmental Protection Agency, and that the scientific literature does not support an association between any of the metals and ovarian cancer.[26] As such, Dr. Tuttle opines that there is no scientific basis for plaintiffs' experts' opinion that heavy metals contribute to talcum powder's alleged causal relationship with ovarian cancer.[27] In so opining, Dr. Tuttle highlights that "[n]one of plaintiffs' experts examines the role of ***dose*** in the assessment of heavy metal in talcum powder."[28]

With respect to fragrances, Dr. Tuttle conducted a review of the relevant scientific literature, including literature searches for mechanistic or epidemiologic studies linking the fragrant chemicals noted by plaintiffs' experts with ovarian cancer in humans.[29] Dr. Tuttle evaluated each of the fragrant ingredients for its potential as a carcinogen as well as its potential as an irritant, sensitizer or allergen.[30] Based on her evaluation, she concluded that none of the fragrant

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26 (*Id.* at 45.)

27 (*Id.*)

28 (*Id.* (emphasis added).)

29 (*Id.* at 46-53.)

30 (*Id.*)

chemicals noted by plaintiffs' experts has been associated with ovarian cancer, and that plaintiffs' experts ignore that the chemical components at issue make up an extremely low percentage of the Products.[31] She also opines that plaintiffs' experts' opinions regarding irritation, sensitization and inflammation in associating those chemicals with ovarian cancer are inherently flawed because they once again disregard the ***dose*** required for irritation, sensitization or inflammation and also misrepresent the mechanisms of carcinogenicity and basic toxicological principles.[32]

C. H. Nadia Moore, Ph.D.

Dr. Nadia Moore is a Principal Toxicologist at Veritox, Inc. with more than 25 years of multidisciplinary experience in toxicology, regulatory compliance, molecular biology and analytical chemistry.[33] She holds a Bachelor of Science in Chemistry with a biochemistry emphasis from Pacific Lutheran University and a Ph.D. in Environmental Toxicology from the University of Washington, School of Public Health and Community Medicine.[34] She is certified in toxicology as a Diplomate of the American Board of Toxicology and is admitted to both the

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31 (*Id.* at 53.)

32 (*Id.*)

33 (Expert Report of H. Nadia Moore, Ph.D., DABT, ERT ("Moore Rep.") at 3, Feb. 25, 2019 (attached as Ex. C19 to Tersigni Cert.).)

34 (*Id.* at 4.)

United Kingdom and Eurotox registries as a European Registered Toxicologist.[35] Dr. Moore is a member of numerous organizations within her field, including the Society of Toxicology, American College of Toxicology, and the British Toxicology Society.[36] She currently serves on the Awards Committee of the Women in Toxicology Specialty Interest Group for the Society of Toxicology and as President for the Pacific Northwest Association of Toxicologists.[37] As part of her daily practice as a toxicologist, Dr. Moore has experience integrating datasets from multiple disciplines, including exposure science, molecular biology, cancer biology, physiology and epidemiology to understand toxicology issues.[38] She has performed studies on the biological effects of inhalation of particulate matter, including studies related to the propensity of particles to cause cancer.[39] She has also presented research on ovarian cancer at the American Industrial Hygiene Conference and Expo, an annual meeting of industrial hygienists.[40]

Dr. Moore opines that: (1) if talcum powder products contained asbestos fibers at the maximum level alleged by plaintiffs' experts Drs. William Longo and

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35 (*Id.* at 3.)

36 (*Id.*)

37 (*Id.* at 4.)

38 (Dep. of H. Nadia Moore, Ph.D. ("Moore Dep.") 126:8-13, 132:13-19, Apr. 4, 2019 (attached as Ex. B27 to Tersigni Cert.).)

39 (*Id.* 187:7-19.)

40 (*Id.* 188:19-189:5.)

Mark Rigler, the concentration would still be far below the level associated with ambient, background exposure and even further below the allowable workplace exposure levels; (2) no association has been found between the alleged metal contaminants (chromium, cobalt and nickel) and ovarian cancer in animals or humans; and (3) there is no support for the concept that fragrance ingredients used in the Products cause ovarian cancer either.[41] She bases these conclusions on her review of case materials, review and analysis of published literature, and application of fundamental toxicology principles, including consideration of both hazard and dose.[42]

Specifically, Dr. Moore opines that, "using conservative assumptions of all other factors (use, frequency, duration)," the exposure concentration purportedly measured by Drs. Longo and Rigler would result in cumulative lifetime exposure that is ***at least 4,000 times below*** the lifetime asbestos concentration associated with the Occupational Safety and Health Administration's ("OSHA's") permissible exposure limit; and "***at least 29,000 times below*** the level of tremolite asbestos considered protective of mesothelioma."[43]

With respect to chromium, cobalt and nickel, Dr. Moore opines that human exposure to these earth metals is ubiquitous and that no association has been found

41 (Moore Rep. at 50, 56, 62, 68, 106.)

42 (*Id.* at 106.)

43 (*Id.* at 50 (emphasis added).)

between these metals and ovarian cancer in humans or animals.[44] Dr. Moore further opines that plaintiffs' experts' Drs. Carson, Plunkett and Cook's failure to characterize the dose at which the heavy metals allegedly contribute to ovarian cancer development is inconsistent with generally accepted methods used by toxicologists to analyze and assess risk to human health.[45]

Finally, Dr. Moore concludes that scientific data do not support the concept that the fragrances present in the Products cause ovarian cancer.[46] Dr. Moore reached her conclusions through extensive research that included a review of industry standards as well as the relevant scientific literature. Dr. Moore also assessed the dose levels of these ingredients and criticizes plaintiffs' experts for ignoring dose in reaching their unreliable causation opinions.[47]

ARGUMENT

I. DR. MOSSMAN'S OPINIONS SHOULD NOT BE EXCLUDED.

Rather than focus on Dr. Mossman's core opinions, plaintiffs offer a hodgepodge of arguments that mainly address: (1) epidemiological studies involving talc and ovarian cancer, a topic that arose at Dr. Mossman's deposition but is not addressed in her report; (2) Dr. Mossman's supposed cherry-picking of

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44 (*Id.* at 50-65.)

45 (*Id.* at 55, 61, 68, 106.)

46 (*Id.* at 68.)

47 (*Id.* at 73-74.)

scientific data; and (3) the reliability of Dr. Mossman's observations regarding the purported migration of talc particles from the perineum to the ovaries. Plaintiffs also very briefly address certain of Dr. Mossman's critiques of Dr. Saed's and Dr. Zelikoff's opinions, which they contend are "mistaken."[48] These arguments are meritless and should be rejected.

A. Plaintiffs' Epidemiology-Based Arguments Are Moot.

Plaintiffs first argue that Dr. Mossman "primarily bases her opinions on her review of the epidemiology," but did not "review[] the totality of the epidemiologic evidence."[49]

This argument fails at the threshold because it is based on a false premise. Dr. Mossman did ***not*** "primarily" base her opinions on a review of epidemiology; indeed, her report does ***not*** address the body of epidemiology that has considered whether perineal talc use is associated with ovarian cancer. Rather, she only addressed that topic at her deposition because she was asked about it.[50] The fact that Dr. Mossman answered questions she was asked at her deposition about the various observational studies involving talcum powder products and ovarian cancer

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48 (*See* Pls.' Steering Committee's Mot. to Exclude the Ops. of Defs.' Toxicology Experts Brooke T. Mossman, M.S., Ph.D., Kelly S. Tuttle, Ph.D., and H. Nadia Moore, Ph.D. ("Pls.' Br.") at 11-28, May 7, 2019 (ECF No. 9739-1).)

49 (*Id.* at 13-14.)

50 (Mossman Dep. 139:13-20; *see also, e.g., id.* 139:23-156:22.)

was not intended to alter the scope of her opinions.[51] *Cf. Broyles v. Cantor Fitzgerald & Co.*, Nos. 10-854-JJB-CBW, 10-857-JJB-CBW, 2016 U.S. Dist. LEXIS 74597, at *9-10 (M.D. La. June 7, 2016) (denying defendants' motion to exclude testimony as moot where the plaintiffs conceded that the testimony was outside the scope of the expert's report and plaintiffs had no intention of proffering such testimony at trial "but point[ed] out that the statement was made in response to a question asked by the defendants' counsel during [the expert's] deposition"). This part of plaintiffs' motion should therefore be rejected as moot.[52]

B. Dr. Mossman Did Not Cherry-Pick Biologic Data.

Plaintiffs offer a laundry list of examples in support of their argument that Dr. Mossman "intentionally chose not to investigate and failed to consider the totality of the biologic evidence relevant to the talc-ovarian cancer question."[53]

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[51] (*See id.* 123:13-15 (testifying that the scope of the opinions in her report constitutes "***all*** of [her] opinions in this case") (emphasis added).)

[52] Plaintiffs also accuse Dr. Mossman of making "demonstrably incorrect statements" in answering their questions related to epidemiology. (*See* Pls.' Br. at 16-17.) But such charges are based on a distortion of Dr. Mossman's actual testimony. Most notably, plaintiffs claim that, "[w]ith the exception of the Penninkilampi study, [Dr. Mossman] testified that the talc meta-analyses performed to date did not show a ***statistically*** significant increased risk of ovarian cancer." (*Id.* at 16 (emphasis added).) However, Dr. Mossman actually testified that the other meta-analyses found that "there is not a ***significantly*** increased risk of ovarian cancer that's related to dose dependency of talc" – i.e., that the association is weak (Mossman Dep. 184:1-4 (emphasis added)) – which is entirely correct, as discussed in great detail in defendants' Memorandum of Law in Support of Motion to Exclude Plaintiff's Experts' Opinions on General Causation.

[53] (Pls.' Br. at 19.)

Specifically, plaintiffs claim that Dr. Mossman: (1) failed to consider any data from animal experiments since 2006; (2) ignored internal J&J documents reflecting historical testing of talcum powder products; (3) did not account for unpublished and draft materials, such as the Taher 2018 manuscript and the 2018 Health Canada Draft Assessment; (4) ignored the IARC 2012 Monograph in formulating her opinion regarding fibrous talc; and (5) failed to report certain findings from the Shukla study, which she co-authored, that supposedly undermine her opinions in this litigation.[54] As discussed below, plaintiffs' arguments are meritless.[55]

First, plaintiffs argue that Dr. Mossman's opinions are unreliable because she did "not consider any of the data from animal experiments since 2006."[56] But this is false. Dr. Mossman's consideration of animal studies after 2006 is evident in her detailed discussion of the Keskin 2009 rat study.[57] As discussed in her report, the authors of that study did not find that talc caused neoplastic changes to

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54 (*See id.* at 19-23.)

55 In responding to these arguments, the J&J defendants also incorporate their response to plaintiffs' omnibus *Daubert* brief, which explains that plaintiffs both misapprehend the standard applicable to defendants' experts and the body of case law addressing improper cherry-picking of scientific data. (*See* Defs.' Mem. of Law in Resp. to Pls.' Steering Committee's Omnibus Br. Regarding *Daubert* Legal Standard & Scientific Principles for Assessing General Causation ("Omnibus *Daubert* Br. Resp.") at 2-4, 8-10 (filed herewith and incorporated herein).)

56 (Pls.' Br. at 19.)

57 (Mossman Rep. at 41.)

the ovaries of rats.[58] The authors also concluded that the different biological effects of talc and asbestos could be attributed to differences in their physical and chemical properties.[59]

The fact that Dr. Mossman might not have considered ***every single*** animal study is of no moment because "[n]othing in *Daubert* . . . requires an expert to consider every single article on a topic in order to be admitted as an expert." *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2018 WL 4220616, at *5 (S.D. W. Va. Sept. 5, 2018) ("I decline to exclude Dr. Kennelly solely for failing to comment on specific articles in his report."); *see also In re Levaquin Prods. Liab. Litig.*, No. 08-1943(JRT), 2010 WL 8399948, at *10 (D. Minn. Nov. 12, 2010) (if an expert "were not able to discriminate between studies she considered useful and those she did not, she would be required to assess every study of a given topic," which "is not required by *Daubert* or the Rules of Evidence"). Rather, in determining whether an expert engaged in cherry-picking, courts consider whether the expert's choice of literature was systematic and slanted – e.g., whether there is evidence that the "search of the scientific literature was in any other way infirm." *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp.

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58 (*Id.*)

59 (*Id.*) *See also* Keskin et al., *Does Long-Term Talc Exposure Have a Carcinogenic Effect on the Female Genital System of Rats? An experimental pilot study*, 280 Archives Gynecol. Obstet. 925 (2009) (attached as Ex. A85 to Tersigni Cert.).

3d 1291, 1341 (N.D. Fla. 2018).[60] Not only did Dr. Mossman consider studies like the Keskin rat study, but she also considered numerous post-2006 ***human*** studies, which are the best model for understanding talc's effect on the human body, including epidemiological studies that showed no increased risk of mesothelioma in talc miners and millers and pleurodesis studies that found no mesotheliomas or ovarian cancers during patient follow-ups.[61]

Second, plaintiffs also assert that "Dr. Mossman turned a blind eye to internal J&J and Imerys company documents regarding the types of asbestos found in the companies' own testing of the products."[62] However, as Dr. Mossman explained at her deposition, her focus was on "the peer-reviewed literature," an approach that comports with case law recognizing the unscientific nature of internal company documents.[63] *See In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 426-27 (S.D.N.Y. 2016) ("Defendants' experts' failure to confront alleged conflicting statements made by Bayer does not warrant exclusion under *Daubert*" because such materials "are not scientific literature that an expert would

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60 (*See also* Omnibus *Daubert* Br. Resp. at 9-10 (reiterating this principle).)

61 (Mossman Rep. at 23-24.) Plaintiffs' complaint that Dr. Mossman erroneously omitted Dr. Crowley's report in her references is trivial. (*See* Pls.' Br. at 20.) After all, Dr. Mossman expressly states in her report that "the trace chemicals Dr. Crowley lists have not been shown to be carcinogens in humans or animals, even at high amounts," demonstrating that she obviously reviewed the portions of the report that her opinions address. (Mossman Rep. at 36.)

62 (Pls.' Br. at 20.)

63 (Mossman Dep. 159:3-6.)

be expected to confront in the exercise of intellectual rigor in the field."); *see also In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1296 (M.D. Fla. 2007) (rejecting plaintiffs' expert's reliance on manufacturer's internal documents that purportedly "admit[] Accutane causes IBD. If such were true of this case, this [c]ourt could have saved a lot of time-this opinion would have been unnecessary.").

In any event, and more fundamentally, internal testing documents are entirely irrelevant to Dr. Mossman's analysis that nonasbestos cleavage fragments do not present a health risk to humans. In forming her opinion, Dr. Mossman considered the mineralogical differences between cosmetic talc particles, nonasbestos cleavage fragments, and asbestos fibers, whether cosmetic talc particles and nonasbestos cleavage fragments could reach or be retained at disease development sites, the biological effect of cosmetic talc particles and nonasbestos cleavage fragments, the limited potential for chemical and biological reactivity presented by trace amounts of cleavage fragments, and experimental studies on threshold exposure levels to asbestos fibers.[64] Plaintiffs do not identify any internal J&J documents that would be relevant to her opinions on these issues. *See Donlon v. Gluck Grp., LLC*, No. 09-5379 (JEI/KMW), 2011 WL 6020574, at *7 (D.N.J. Dec. 2, 2011) (refusing to exclude the testimony of marine surveyor because "these supposed failures" to conduct various tests on the allegedly

[64] (Mossman Rep. at 15-22.)

defective houseboat "are irrelevant to Scott's opinions regarding measurements and their application to ASTM standards"). For this reason, too, their arguments should be rejected.

Third, plaintiffs also argue that Dr. Mossman cherry-picked from the literature because she failed to consider the recent draft screening assessment of talc by Health Canada and the related meta-analysis by Mohamed Taher on which Health Canada heavily relied.[65] However, these documents do not speak to the issues addressed in Dr. Mossman's report, which primarily focuses on the purported health hazards posed by nonasbestos cleavage fragments. As a result, Dr. Mossman's failure to address them is beside the point and does not constitute evidence that her unrelated opinions are somehow unreliable. In any event, the notion that an expert improperly cherry-picked because she did not cite an unpublished, non-peer-reviewed manuscript and a draft regulatory document from another country that plaintiffs think support their position is absurd on its face. As defendants note in their Omnibus *Daubert* Opposition Brief, plaintiffs' obsessive focus on the unpublished Taher meta-analysis and draft Health Canada report highlights the fact that the real scientific literature offers no support for their speculative and unscientific theories.

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65 (Pls.' Br. at 20-21.)

Fourth, plaintiffs also disingenuously accuse Dr. Mossman of not having "actually reviewed the 2012 IARC Monograph 100c" in formulating her opinions with regard to asbestos and fibrous talc, notwithstanding her citation to – and reliance on – that exact monograph.[66] According to plaintiffs, while Dr. Mossman cites to the IARC Monograph in opining that "[f]ibrous talcs not containing asbestos fibers have not been classified as human carcinogens," the Monograph actually "indicates Group I carcinogenicity applies to ***both*** asbestos and talc containing asbestiform fibers (e.g., fibrous talc)."[67] But plaintiffs – just like their experts who attempt to weigh in on the question of heavy metals – fundamentally misapprehend the IARC Monograph. As elaborated in defendants' Memorandum of Law in Support of Motion to Exclude Plaintiffs' Experts' Opinions Regarding Alleged Heavy Metals and Fragrances in Johnson's Baby Powder and Shower to Shower, although IARC explains that "'[t]alc containing asbestiform fibers' is a term that has been used inconsistently in the literature,'" there is no question that talc products that merely contain elongated mineral fragments, that are not "intergrown" with asbestos – i.e., the talc that certain of plaintiffs' experts call fibrous talc – are ***not*** carcinogenic.[68] Accordingly, not only did Dr. Mossman fully

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66 (*Id.* at 21.)

67 (*Id.* at 21-22 (alteration in original) (second emphasis added).)

68 (Defs.' Mem. of Law in Supp. of Mot. to Exclude Pls.' Experts' Ops. Regarding Alleged Heavy Metals & Fragrances in Johnson's Baby Powder and

review and consider the IARC Monograph's treatment of this concept, but her interpretation of it is entirely accurate.

Fifth, plaintiffs also argue that Dr. Mossman ignored certain of her own data that supposedly undermine her opinions in this litigation.[69] But all of those data pertain to her co-authored Shukla 2009 study, which in no way contradicts Dr. Mossman's opinions here. As Dr. Mossman explains in her report, that study "examined ***gene expression*** in human ovarian epithelial cells, in addition to mesothelial cells."[70] And as elaborated in the J&J defendants' Memorandum of Law in Support of Motion to Exclude Plaintiffs' Experts' Opinions Related to Biological Plausibility, gene expression does not by itself say anything about the ostensible carcinogenicity of talc.[71] Indeed, as Dr. Mossman explained, the experiment did not "attempt[] to show changes with talc carcinogenicity"; talc was simply used as a control.[72] Nonetheless, "[t]hese and additional data were examined subsequently by Hillegass et al. (2010) to show that the effects of talc

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Shower to Shower at 60, May 7, 2019 (ECF No. 9736-4) (alteration in original) (quoting Int'l Agency for Research on Cancer, World Health Org., 100C *Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and Dust* 230 (2012)).)

69 (*See* Pls.' Br. at 22-23.)

70 (*Id.* at 40 (emphasis added).)

71 (Defs.' Mem. in Supp. of Mot. to Exclude Pls.' Experts' Ops. Related to Biological Plausibility ("Defs.' Biological Plausibility Br.") at 60, May 7, 2019 (ECF No. 9736-1).)

72 (Mossman Dep. 362:14-16.)

were comparable to those shown with the negative control particles, fine titanium dioxide and glass beads."[73] In other words, the changes that plaintiffs characterize as "favorable findings" were merely baseline cellular responses to the introduction of foreign substances.[74]

While plaintiffs cite a handful of cases generally addressing the cherry-picking of scientific data and conclusory *ipse dixit* opinions, those cases do not support plaintiffs' arguments because they either ***rejected*** such claims or involved scenarios where – unlike here – experts dismissed contradictory scientific data ***without any scientific basis***. *See, e.g., In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 3806434, at *5-8 (M.D. Fla. June 18, 2009) (cited in Pls.' Br. at 25-26) ("Contrary to AstraZeneca's assertions, Dr. Arnett did not approach the evidence with a preconceived conclusion on causation. . . . [T]he record demonstrates that Dr. Arnett conducted a reasonably thorough review of the

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[73] (Mossman Rep. at 40 (emphases added).) Notably, the Hillegass follow-up study confirmed that gene expression by talc "was significantly different both qualitatively and quantitatively from asbestos" and "equivalent to gene expression by non-cancer causing control particles and untreated cells." (*Id.* at 25.)

[74] Plaintiffs also claim that Dr. Mossman failed to report ATF3's connection to inflammation. (*See* Pls.' Br. at 23.) But this is false, as her report explains that follow-up studies examining ATF3's "functional role in inflammation" revealed that ATF3 is "***anti***-inflammatory and ***inhibits*** early markers of cancer development by asbestos." (Mossman Rep. at 25 (emphases added).) And plaintiffs' claim that Dr. Mossman omitted a favorable finding regarding IL8 is meritless in light of Dr. Mossman's testimony that IL8 "can have opposite effects" with regard to inflammation. (Mossman Dep. 60:17-21.)

clinical data prior to issuing her first report."); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658, 676-77 (S.D. W. Va. 2014) (cited in Pls.' Br. at 25) (excluding plaintiffs' expert who dismissed contradictory studies regarding complication rates and instead gave "the benefit of the doubt to the patient," which "is not a scientific basis for determining the complication rates associated with a mesh device") (citation omitted).[75]

Here, by contrast, plaintiffs' claims of "cherry-picking" and "*ipse dixit*" ring hollow, fundamentally ignoring the litany of scientific data addressed in Dr. Mossman's report (including post-2006 animal studies) and relying on a handful of materials that are unscientific (e.g., internal company documents) and/or irrelevant to Dr. Mossman's opinions (e.g., the Health Canada draft screening assessment and unpublished Taher manuscript). For this reason, too, plaintiffs' arguments should be rejected.

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[75] *See also, e.g.*, *Dow v. Rheem Mfg. Co.*, 527 F. App'x 434, 437 (6th Cir. 2013) (cited in Pls.' Br. at 26) (excluding plaintiffs' design expert's testimony based on "his failure to test the key factor" of his own design-defect theory); *In re Neurontin Mktg. & Sales Practices Litig.*, No. 04-cv-10739-PBS, 2011 WL 3852254, at *34 (D. Mass. Aug. 31, 2011) (cited in Pls.' Br. at 26 n.84) (unreliable to ignore double-blind randomized controlled trials in assessing the safety and efficacy of pharmaceutical drugs, which are the "gold standard" of scientific evidence in that context), *aff'd*, 712 F.3d 21 (1st Cir. 2013).

C. Dr. Mossman's Opinions Related To Biological Plausibility Are Reliable.

With respect to biological plausibility, plaintiffs argue that Dr. Mossman's opinions are not reliable because: (1) she purportedly conflates "plausibility" with "proof"; and (2) her opinion that the migration theory is "not supported by the scientific data"[76] is not based on a complete review of the literature. Both arguments lack merit.

First, plaintiffs argue that Dr. Mossman "recast[s] 'biologic plausibility' as requiring 'biologic proof' and not 'plausibility.'"[77] Not so. As a threshold matter, it is plaintiffs, not Dr. Mossman, who are mistaken about what biological plausibility requires. "[M]erely an unproven ***hypothesis***" does not suffice to establish a mechanism as biologically plausible. *In re Accutane*, 511 F. Supp. 2d at 1295-96 (emphasis added) ("[A] biological explanation without evidence of the mechanism by which it works is merely an unproven hypothesis, a theory."). And while "*Daubert* does not require absolute precision in identifying the medical mechanism of injury, there still must be 'sufficiently compelling proof'" of it. *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 561-62 (W.D. Pa. 2003) (citation omitted).

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76 (Mossman Rep. at 35-37.)

77 (Pls.' Br. at 15; *see also id.* at 23-24 (arguing that Dr. Mossman "improper[ly] conver[ted] . . . 'plausibility' to 'proof,' a concept inconsistent with the Hill analysis of biologic plausibility").)

Dr. Mossman's report and deposition are true to this standard. Her report only mentions "proof" in specifically paraphrasing ***Dr. Zelikoff's*** opinion that "biological plausibility does not mean proof of mechanism."[78] Although Dr. Mossman states that Dr. Zelikoff "has indeed not supplied proof of a mechanism through which talc use causes ovarian cancer," the focus of Dr. Mossman's evaluation is on the "serious methodological deficiencies" Dr. Zelikoff employed "to posit that a mechanism is ***even plausible***."[79]

The portion of Dr. Mossman's deposition testimony cited by plaintiffs in which she rejected plaintiffs' theory of migration also focused on plausibility. For example, Dr. Mossman explained that the 2014 FDA citizen petition response did not offer support for the migration theory – which is entirely correct, inasmuch as the letter does not cite any study or data in support of that conclusion – and concluded that "no balanced committee would make that statement."[80] Her characterization of the migration theory as "unproven" merely borrows from the text of that very response, which states that "there exists no direct proof of talc and ovarian carcinogenesis."[81] Dr. Mossman's understanding that a "hypothesis" is

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78 (Mossman Rep. at 35 (quoting Zelikoff Rep. at 2).)

79 (*Id.* (emphasis added).)

80 (Mossman Dep. 349:17-350:6.)

81 (*Id.* 349:12-350:22 (quoting Letter from Steven M. Musser, Ph.D., Deputy Dir. for Sci. Operations, Ctr. for Food Safety & Applied Nutrition, to Samuel S.

insufficient for demonstrating biologic plausibility is entirely correct and validates the reliability of her opinions on this subject.

Second, plaintiffs also make the unfounded claim that Dr. Mossman has not "familiarized herself with the literature" on migration, resting this assertion entirely on a few lines of deposition testimony in which she ostensibly "admitted she has not studied the topic" of migration.[82] Not so. What Dr. Mossman actually stated was that she has not ***performed*** any "studies" examining whether there is a scientifically plausible pathway for cosmetic talc to migrate to the ovaries or fallopian tubes.[83] Of course, the fact that Dr. Mossman has not undertaken any specific studies herself is not a legitimate ground for excluding her migration-related opinions, which are based on her familiarity with the body of scientific literature examining migration. *See In re Mirena*, 169 F. Supp. 3d at 419-20 ("Although [defense OB/GYN] has not performed any studies herself, this does not mean she is not qualified to give a medical opinion [on causation] using her experience as well as a review of relevant scientific literature.").

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Epstein, M.D., Cancer Prev. Coalition, Univ. of Ill. – Chi. School of Pub. Health, at 5 (Apr. 1, 2014)).)

82 (Pls.' Br. at 23-24.)

83 (Mossman Dep. 210:24-211:5.)

D. Plaintiffs' Cursory Challenges To Dr. Mossman's Critiques Of Their Own Experts Fail.

Plaintiffs also briefly argue that Dr. Mossman offers various "mistaken criticisms of plaintiffs' experts [Drs. Saed and Zelikoff] regarding their causation opinions."[84] Once again, plaintiffs' arguments are meritless

1. Dr. Mossman's Critiques Of Dr. Saed's Opinions Are Reliable.

Plaintiffs ignore the overwhelming majority of Dr. Mossman's specific and fundamental criticisms with regard to Dr. Saed, including his misinterpretation of the relevant scientific literature, his misrepresentation of the data from his studies, and his unethical manipulation of his lab notebooks.[85] Instead, plaintiffs focus solely on Dr. Mossman's discussion of Dr. Saed's failure to disclose the source of funding for his talc research and the litigation-driven nature of his research.

Plaintiffs' first argument – that "Dr. Mossman is wrong" in claiming that Dr. Saed failed to disclose the source of funding for his talc research – is both disingenuous and false.[86] For one thing, plaintiffs well know that Dr. Mossman submitted her report on February 25, 2019, and the final manuscript in which the language about Dr. Saed's potential conflicts was changed was not published until a few days later. But even if that final manuscript had been available when Dr.

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84 (Pls.' Br. at 17.)

85 (Mossman Rep. at 27-30, 32-34.)

86 (Pls.' Br. at 17.)

Mossman completed her expert report, it still fails to properly disclose the source of Dr. Saed's funding because it represented that the "author(s) received no financial support for the research, authorship, and/or publication of this article."[87] Dr. Saed's deposition testimony makes it clear that this representation was false.[88] Thus, this criticism of Dr. Mossman has zero basis in reality.

Plaintiffs also claim that Dr. Mossman "makes unfounded claims" regarding Dr. Saed's litigation-driven motivations because "the vast majority of Dr. Saed's research in this area was conducted prior to his involvement in this litigation."[89] But once again, it is ***plaintiffs*** who are making unfounded claims. After all, as Dr. Saed expressly acknowledged, he had not conducted any studies involving talc prior to being approached by plaintiffs' counsel in this litigation.[90] Far less had he "done anything like" applying talc to cells before he was approached by plaintiffs' counsel.[91] When plaintiffs' counsel contacted him about possibly serving as an expert, Dr. Saed told them that he did not have "any molecular data in [his] laboratory to support the direct effect of talcum powder on [the] markers [he]

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87 *See* Fletcher et al., *Molecular Basis Supporting the Association of Talcum Powder Use With Increased Risk of Ovarian Cancer*, *Reproductive Sciences* 1, 9 (2019) ("Saed Article") (attached as Ex. A39 to Tersigni Cert.).

88 (Dep. of Ghassan Saed, Ph.D. Vol. 1 ("Saed 1/23/19 Dep.") 33:22-34:9, Jan. 23, 2019 (attached as Ex. B12 to Tersigni Cert.).)

89 (Pls.' Br. at 17-18.)

90 (Saed 1/23/19 Dep. 27:12-15.)

91 (*Id.* 62:16-23.)

studied in [his] lab," but he "would like to do that."[92] This testimony from Dr. Saed lays bare the litigation-motivated nature of his research, which Dr. Mossman rightfully and reliably points out in her report.

2. Dr. Mossman's Critiques Of Dr. Zelikoff Are Reliable.

Plaintiffs also argue that Dr. Mossman's criticisms of Dr. Zelikoff "are without merit" because Dr. Zelikoff's report "is replete with citations" from the "peer-reviewed scientific literature."[93] Of course, this argument ignores the fact that many statements in Dr. Zelikoff's report were plagiarized from the internet without citations.[94] But even putting that aside, plaintiffs fundamentally misperceive the point of Dr. Mossman's critiques of Dr. Zelikoff, which is not that Dr. Zelikoff failed to cite studies, but rather that she "incorrectly characterizes" those studies.[95] For example, plaintiffs assert that Dr. Zelikoff relied on more than 30 peer-reviewed publications in support of her migration opinions.[96] But they do not address Dr. Mossman's criticism of that reliance, which is that Dr. Zelikoff "cite[d] a series of studies performed decades ago where boluses of talc were applied intravaginally or within the uterus, **not** externally to the perineum," and

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92 (*Id.* 275:24-276:5.)

93 (Pls.' Br. at 18.)

94 (*See* Mossman Rep. at 35.)

95 (*Id.* at 39.)

96 (Pls.' Br. at 19.)

that Dr. Zelikoff acknowledged that "there are no studies showing that talc applied externally (i.e., to the perineum) migrates to the ovaries."[97] Similarly, although Dr. Zelikoff relies on the Shukla study to support her theory of biological plausibility, as plaintiffs note in their brief,[98] that study examined gene expression, not carcinogenicity, as already discussed. Moreover, Dr. Mossman and her colleagues found that inert particles (the experimental control) and talc particles had ***identical*** effects on gene expression in peritoneal mesothelioma cells, meaning that the changes that plaintiffs characterize as "favorable findings" were just baseline cellular responses to the introduction of foreign substances, rather than any evidence of a causal relationship between talc and ovarian cancer.[99] In short, the example provided by plaintiffs only underscores the unreliability of their own expert's opinion, which Dr. Mossman appropriately explains in her report.

For all of these reasons, plaintiffs' arguments do not warrant exclusion of any of Dr. Mossman's opinions.

II. DR. TUTTLE'S OPINIONS SHOULD NOT BE EXCLUDED.

Plaintiffs similarly argue that Dr. Tuttle is not qualified to offer general causation opinions in this litigation and that her opinions regarding biological plausibility are unreliable. As elaborated below, both arguments are meritless.

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97 (Mossman Rep. at 37.)

98 (Pls.' Br. at 19.)

99 (*See* Mossman Dep. 453:21-454:9.)

A. Dr. Tuttle Is Qualified To Offer General Causation Opinions.

The Third Circuit "interpret[s] Rule 702's qualification requirement liberally," *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) – a proposition reiterated by plaintiffs' own authority, *see, e.g.*, *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (cited in Pls.' Br. at 28) ("We have interpreted this requirement liberally . . . .") (citation omitted); *Elcock v. Kmart Corp.*, 233 F.3d 734, 742 (3d Cir. 2000) (cited in Pls.' Br. at 29) ("This court has had, for some time, a generally liberal standard of qualifying experts."). Under this "liberal[]" interpretation, the Court of Appeals has recognized that a "broad range of knowledge, skills, and training qualify an expert." *Pineda*, 520 F.3d at 244 (citation omitted); *see also Calhoun*, 350 F.3d at 321 (same); *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002) (noting that the Third Circuit has "eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more general qualifications") (citation omitted), *aff'd*, 68 F. App'x 356 (3d Cir. 2003). As a result, "most arguments about an expert's qualifications relate more to the weight to be given the expert's testimony than to its admissibility." *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782-83 (3d Cir. 1996) (rejecting argument that board-certified physician in internal and pulmonary medicine was unqualified to testify about the causes of mesothelioma).

Plaintiffs nonetheless argue that Dr. Tuttle fails to satisfy this "liberal" standard and is unqualified to offer her general causation opinions because: (1) she is not an epidemiologist and has not previously employed a Bradford Hill analysis with respect to a ***manufactured*** product (even though she has conducted such analyses in other contexts); and (2) she recycled boilerplate sections of her report from reports that she and her colleagues had previously submitted in other litigation.[100] As set forth below, plaintiffs' arguments distort the breadth of Dr. Tuttle's expertise, misapply the relevant law and falsely accuse her of plagiarism.[101]

First, plaintiffs argue that the "twelve pages focused on epidemiological information" within Dr. Tuttle's report are beyond the scope of her expertise because she "is a toxicologist and industrial hygienist" as opposed to an epidemiologist.[102] "However, the Third Circuit rejected an analogous argument . . . , reversing a district court that excluded a toxicologist's causation testimony on those grounds." *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 659 (E.D. Pa. 2012) (citing *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 855-56

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100 (Pls.' Br. at 30-31.)

101 As elaborated in the J&J's defendants' response to plaintiffs' omnibus *Daubert* brief, plaintiffs advance a double standard with regard to qualifications. (*See* Omnibus *Daubert* Br. Resp. at 5.) The J&J defendants fully incorporate that brief herein. (*See id.* at 5-8.)

102 (Pls.' Br. at 29.)

(3d Cir. 1990)). As the Third Circuit explained in that case, "[t]he district court's insistence on a certain kind of degree or background is inconsistent with our jurisprudence in this area." *In re Paoli*, 916 F.2d at 855. Rather, "[i]n light of the liberal Rule 702 expert qualification standard," the Court of Appeals held that the expert's background and education in toxicology and "extensive research" in that field more than qualified her to opine on the fundamental question of causation. *Id.* at 855-56. The district court in *Wolfe* reached the same conclusion, applying *In re Paoli* and holding that an expert's expertise as a toxicologist and familiarity with the epidemiological studies "qualifie[d] him to present causation testimony." 881 F. Supp. 2d at 659; *see also Wells v. Allergan, Inc.*, No. CIV-12-973-C, 2013 WL 7208337, at *1 (W.D. Okla. Feb. 7, 2013) (party making qualifications argument "did not cite a single case where a court has required a causation expert to be an epidemiologist. In fact, this proposition is contrary to practice in this Circuit.") (footnote omitted).[103]

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[103] The limited authorities cited by plaintiffs either support ***defendants'*** position or are utterly inapposite. For example, in *Elcock*, the Third Circuit ***affirmed*** the district court's holding that a psychologist ***was*** sufficiently qualified to opine about the extent of the plaintiff's vocational rehabilitation even though he had "no formal training in vocational rehabilitation" because, *inter alia*, he "kept abreast of the relevant literature in his field"; attended conferences regarding vocational rehabilitation; and "no doubt performed his brand of vocational rehabilitation assessments" as part of his experience as an expert in prior cases. 233 F.3d at 743-44. And in *Calhoun*, 350 F.3d at 323 (cited in Pls.' Br. at 28-29), the Third Circuit held that the district court did not abuse its discretion in merely limiting the testimony of three different experts (a psychologist, a marine safety expert and a

The same result is called for here. As elaborated in Dr. Tuttle's report, not only does Dr. Tuttle have a Ph.D. degree in Toxicology, but she has "been actively involved in the areas of toxicology, human health risk assessment, and emergency response"; she has been a member of the Society of Toxicology and various other organizations; and she has written peer-reviewed articles in toxicology and related fields.[104] Further, "[a]s a toxicologist, [Dr. Tuttle] routinely assist[s] in the determination of disease causation by evaluating chemical exposure and the scientific evidence relating exposure to human diseases according to the methodology of toxicological causation analysis."[105] "This experience qualifies

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naval architecture/marine engineering expert) with regard to safety ***warnings*** because that subject was not remotely related to the scope of their expertise. *Id.* at 322-24. As courts distinguishing *Calhoun* have made clear, an expert "satisfies the qualifications criterion" where – as here – his expertise "relate[s]" to the "subject about which he testifies." *McManus v. Barnegat Rehab. & Nursing Ctr.*, No. 15-2109 (BRM)(LHG), 2018 U.S. Dist. LEXIS 88955, at *13-14 (D.N.J. May 29, 2019) ("Mr. Cocchiola's qualifications relate to mechanical engineering, which is the subject about which he testifies. This is distinguishable from the disqualification of the marine safety expert and a naval architecture/marine engineering expert called to testify about safety warnings in *Calhoun*."); *McKenzie v. Dematic Corp.*, No. 3:12-250, 2016 U.S. Dist. LEXIS 21256, at *10 (W.D. Pa. Feb. 22, 2016) ("Unlike the cases cited by [d]efendants, [including *Calhoun*,] Professor deVries has both training and work experience that relate to the design of conveyor systems, and he seeks to testify about the relationship between a conveyor system and a building.").

104 (Tuttle Rep. at 1.)

105 (*Id.*)

h[er] to present causation testimony," notwithstanding her lack of formal training as an epidemiologist. *Wolfe*, 881 F. Supp. 2d at 659.

In their motion, plaintiffs emphasize that Dr. Tuttle has never taken a course that required an epidemiology textbook and never reviewed what ***plaintiffs*** regard as the "leading textbook on epidemiology."[106] But the textbook at issue – unsurprisingly authored by Kenneth Rothman,[107] whom plaintiffs cite throughout their briefing for a range of propositions that have not gained broad scientific acceptance – expressly challenges the ***consensus*** that case-control studies are inferior to cohort studies. By its nature, a challenge to scientific consensus on an issue cannot be regarded as the "leading" authority in the field on that topic, as elaborated in the J&J defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Exclude the Opinions of Defendants' Epidemiology Experts.[108] Moreover, plaintiffs' argument is tantamount to the very sort of "insistence on a certain kind of degree or background" that "is inconsistent with" the Third Circuit's "jurisprudence in this area." *In re Paoli*, 916 F.2d at 855.

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106 (Pls.' Br. at 29.)

107 Rothman et al., *Modern Epidemiology* (3d ed. 2008).

108 (*See* Defs.' Mem. of Law in Supp. of Opp'n to Pls.' Mot. to Exclude the Ops. of Defs.' Epidemiology Experts at 32 n.94 (filed herewith and incorporated herein).) Plaintiffs' repeated reliance on this textbook is all the more illogical given that one of its authors, Kenneth Rothman, has concluded that a causal relationship has not been established between talc and ovarian cancer. *See* Rothman et al., *Interpretation of Epidemiologic Studies on Talc and Ovarian Cancer* at 1 (2000) (attached as Ex. A126 to Tersigni Cert.).

In any event, plaintiffs ignore that Dr. Tuttle has in fact "studied" epidemiology as "part of [her] training and expertise in toxicology."[109] Indeed, such experience is no different from that of plaintiffs' own toxicology expert, Dr. Plunkett, who (despite not being an epidemiologist "by training"), nonetheless claims to "use [it] all the time."[110] Nor is it any different from the experience of plaintiffs' other toxicologist, Dr. Arch Carson, who similarly addresses the topic of epidemiology even though he is not an epidemiologist and did not train in epidemiology.[111] In short, Dr. Tuttle is no less qualified than plaintiffs' own toxicologists to opine on subjects that touch on epidemiology, confirming that plaintiffs are advancing an unsupportable double standard on the question of qualifications.

Plaintiffs also highlight that Dr. Tuttle has never used the Bradford Hill criteria to "assess the safety of a ***manufactured*** product."[112] However, as even plaintiffs are forced to acknowledge, Dr. Tuttle employs those criteria "'***regularly*** in assessing the scientific literature in the body of science'"[113] And such regular

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109 (Dep. of Kelly Scribner Tuttle, Ph.D. ("Tuttle Dep.") 81:17-19, Apr. 11, 2019 (attached as Ex. Q to Pls.' Br.).)

110 (Dep. of Laura Plunkett, Ph.D., D.A.B.T. 356:3-7, Dec. 19, 2018 (attached as Ex. B33 to Tersigni Cert.).)

111 (*See, e.g.*, Dep. of Arch I. Carson, M.D., Ph.D. 61:17-19, Jan. 19, 2019 (attached as Ex. B5 to Tersigni Cert.).)

112 (Pls.' Br. at 30 (emphasis added).)

113 (*Id.* (emphasis added).)

experience more than qualifies Dr. Tuttle to apply the Bradford Hill factors to any product (manufactured or otherwise). *See In re Roundup Prods. Liab. Litig.*, No. 16-md-02741-VC, 2018 U.S. Dist. LEXIS 114760, at *124 (N.D. Cal. July 10, 2018) (biostatistician with focus on toxicology was qualified to conduct Bradford Hill analysis as to manufactured product; "although epidemiology is not his core area, he is qualified to examine the epidemiology literature to see whether an association exists and, if so, to engage in a Bradford Hill analysis"); *see also Betterbox Commc'ns Ltd. v. BB Techs., Inc.*, 300 F.3d 325, 328 (3d Cir. 2002) ("Schulte's lack of experience in marketing the ***precise type of computer components*** sold by these companies does not establish that the [d]istrict [c]ourt abused its discretion in ruling that his qualifications met the standard of Rule 702.") (emphasis added).

While plaintiffs also assert that Dr. Tuttle's deposition testimony "demonstrated that she lacks a basic understanding of epidemiologic concepts,"[114] the only example they cite tells a different story. Specifically, plaintiffs claim that Dr. Tuttle was "unable" to define the term "confounding" despite using it throughout her report, quoting her testimony that "any definition [she] would offer . . . would be . . . [her] interpretation or [her] kind of summation without

[114] (Pls.' Br. at 29.)

having . . . what [she] ha[s] in [her] report." [115] However, in the very next answer she provided – which plaintiffs omit from their discussion – Dr. Tuttle explained that "we're speaking in generalities, and without looking at these studies, confounding may mean something slightly different depending on the study and what the authors are doing."[116] Thus, far from evincing a lack of understanding of basic epidemiologic principles, Dr. Tuttle's testimony demonstrates that she was faithfully and meticulously adhering to the teachings of that discipline.

For all of these reasons, plaintiffs' preoccupation with Dr. Tuttle's lack of formal training as an epidemiologist and failure to conduct Bradford Hill analyses with respect to ***manufactured*** products in particular contravenes the Third Circuit's "liberal" qualifications standard and should be rejected.

Second, plaintiffs also attempt to manufacture a "qualifications" argument by baldly asserting that Dr. Tuttle "plagiarized large segments of her report from [two] prior reports submitted by a more senior toxicologist at ***her company*** in unrelated litigation."[117] But recycling the work product of a colleague with whom Dr. Tuttle has collaborated is simply ***not*** plagiarism, and plaintiffs do not even attempt to cite any authority suggesting – much less holding – that it is. As Dr.

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115 (*Id.* at 29-30 (quoting Tuttle Dep. 156:5-11).)

116 (Tuttle Dep. 156:17-24.)

117 (Pls.' Br. at 30 (emphasis added).)

Tuttle explained, employees at her firm work as a "team"[118]; indeed, Dr. Tuttle was part of the team that worked on *Watson v. BNSF Railway Co.*, the case that generated one of the two prior reports that is the focus of plaintiffs' argument. Moreover, even a cursory review of the exhibit comparing Dr. Tuttle's report to the two prior ones submitted by her colleague demonstrates that the recycled portions pertain to such background and uncontroversial matters as how "senior toxicologists" at Dr. Tuttle's firm describe their duties and responsibilities; how such individuals define the field of toxicology; how such individuals define basic concepts of general and specific causation; and how they delineate the contours of basic principles related to dose and exposure outside the specific context of talc.[119]

Dr. Tuttle's benign recycling of these boilerplate concepts is a far cry from the actual plagiarism that mars the report of ***plaintiffs'*** expert, Dr. Zelikoff, who conceded that she copied verbatim from the internet and from other experts.[120] As elaborated in defendants' Memorandum in Support of Motion to Exclude Plaintiffs' Experts' Opinions Related to Biological Plausibility, Dr. Zelikoff's report even contains several identical sentences and paragraphs to those contained in certain of

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118 (Tuttle Dep. 96:16-21.)

119 (*See* Demonstrative Comparing Dr. Tuttle's Expert Report with the 2012 and 2016 Expert Reports of Dr. Kind (attached as Ex. S to Pls.' Br.).)

120 (Dep. of Judith Zelikoff, Ph.D. ("Zelikoff Dep.") 96:8-97:2, 102:21-106:8, 115:17-119:17, 119:22-121:13, Jan. 21, 2019 (attached as Ex. B31 to Tersigni Cert.).)

plaintiffs' other experts' reports, which is particularly odd since all the reports were signed on the same day.[121] And critically, the plagiarized portions of Dr. Zelikoff's report do not go to mere background points. Rather, as discussed in Dr. Moore's report, the copied passages relate to core issues, such as the carcinogenicity of nickel and the origins of genetic mutations and their relationship to disease risk.[122] Plaintiffs' efforts to project their experts' methodological flaws onto defendants' experts should be soundly rejected.

B. Dr. Tuttle's Opinions Are Based On A Proper Methodology.

Plaintiffs also argue that "Dr. Tuttle failed to employ generally accepted methodology in rendering her toxicology opinions."[123] But in so arguing, they only attack a tiny sliver of her opinions (those related to biological plausibility), while ignoring the core of her toxicology opinions. Plaintiffs' failure to address these central opinions (including her opinions on heavy metals and fragrances) is an effective concession that they are reliable and admissible.

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121 (*See* Defs.' Biological Plausibility Br. at 69-70.)

122 (*See* Moore Rep. at 100 (Dr. Zelikoff copied a discussion about the "mechanisms of nickel-induced carcinogenesis"); *id.* at 101 (Dr. Zelikoff copied discussion about the "accumulation of nickel in the . . . body") (alteration in original); *id.* (Dr. Zelikoff copied discussion about "[t]he marked differences in the carcinogenic activities of various nickel compounds"); *id.* (Dr. Zelikoff copied discussion about "nickel compounds induc[ing] tumors at virtually all sites of application"); *id.* at 102 (Dr. Zelikoff copied discussion about "disease-causing gene mutations").)

123 (Pls.' Br. at 32.)

While plaintiffs do seek to discredit Dr. Tuttle's more limited opinions related to biological plausibility, their arguments on that score boil down to the claim that Dr. Tuttle engaged in a "*post hoc* style of scientific evaluation" whereby she "first referred to other experts' work and opinions, then looked to the scientific literature to generate the conclusion she already had."[124] As a threshold matter, this criticism is nonsensical inasmuch as Dr. Tuttle necessarily had to first evaluate plaintiffs' experts' opinions and their bases in order to determine what she was responding to; thus, the fact that she informed herself on this score before she began her research is not only unremarkable but a fundamental prerequisite to

[124] (*Id.* at 39.) The only supposed "reliability" objections that are not tethered to Dr. Tuttle's biological plausibility opinions are that: (1) Dr. Tuttle "could not identify any appropriate hazard assessment methodology" "[d]espite asserting she is trained to perform hazard assessments and has performed them in the past" (*id.* at 33, 35); and (2) Dr. Tuttle supposedly "disagrees with th[e] generally accepted view" that "scientists evaluating the same data can reach different conclusions regarding a given question." (*Id.* at 35.) Neither challenge has any merit. As to the former claim, a more fulsome review of Dr. Tuttle's testimony merely illustrates that various government agencies apply different kinds of risk assessments. (*See* Tuttle Dep. 58:12-14 ("There are some guidelines in the regulatory agencies in regards to hazard assessment.").) This testimony is in accord with Dr. Tuttle's report, which makes clear that "[s]everal agencies assess the evidence of carcinogenic risks to humans and have derived criteria and classifications based upon the state of the scientific research." (Tuttle Rep. at 13.) As to the latter claim, Dr. Tuttle merely testified that scientists who "are looking at the ***same body of science and applying the same methodology***" should "arrive at the same conclusions." (Tuttle Dep. 122:21-123:2 (emphasis added).) Such testimony is hardly a basis for deeming her opinions unreliable, particularly given the broader context of her testimony, which was that "[t]he science is the science" and "[y]ou have to just look at the body of science as it stands and look at what it shows." (*Id.* 121:17-19; *see also id.* 121:5-16.)

doing her work reliably. To the extent plaintiffs mean to suggest that Dr. Tuttle reached a conclusion first and then backfilled it with cherry-picked sources from her research, the accusation is simply made up. Even the testimony cited by plaintiffs makes clear that Dr. Tuttle "reviewed the scientific literature" prior to reaching her conclusions.[125] In any event, plaintiffs' argument ignores that Dr. Tuttle's opinions are largely couched in terms of criticizing plaintiffs' experts' theories of biological plausibility, which (as already discussed), is an "entirely appropriate" approach. *In re Abilify*, 299 F. Supp. 3d at 1368. As discussed below, application of the proper standard demonstrates that Dr. Tuttle's biological plausibility opinions are methodologically sound and admissible.

1. Dr. Tuttle's Opinions On Migration Are Reliable.

As the testimony highlighted in plaintiffs' brief makes clear, Dr. Tuttle "'reviewed the scientific literature regarding the migration theory and whether there's any scientific evidence to support the [theory that] perineal application of talcum powder can reach the ovaries.'"[126] Based on that review, Dr. Tuttle concluded that ***plaintiffs'*** experts' migration theory "is severely flawed" and not "scientifically sound."[127] Specifically, as discussed in Dr. Tuttle's report, Dr.

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125 (*Id.* 130:19-131:2.)

126 (Pls.' Br. at 39 (quoting Tuttle Dep. 130:19-131:2).)

127 (Tuttle Rep. at 57 (criticizing Dr. Plunkett's theory of particle migration); *id.* at 60 (criticizing Dr. Zelikoff's migration theory).)

Plunkett's migration theory is at odds with IARC's conclusion that "the evidence for retrograde transport of talc to the ovaries in normal women is weak" and "animal studies have '*show[n] no evidence of retrograde transport of talc to the ovaries*.'"[128] Further, as set forth in Dr. Tuttle's report, one of the studies cited by Dr. Plunkett herself "*found that 'talc particles were observed to a similar extent with both exposed and unexposed subjects*," undermining any suggestion that the mere presence of talc particles in ovarian tissue suffices to support plaintiffs' theory of migration.[129] At bottom, these opinions are, "essentially, critiques of [p]laintiffs' experts' evidence, methodologies, and conclusions," which "[is] entirely appropriate" under Rule 702. *In re Abilify*, 299 F. Supp. 3d at 1368.

In their motion, plaintiffs nonetheless urge the Court to exclude these critiques on the ground that they constitute mere "*ipse dixit*." In so urging, plaintiffs argue that: (1) Dr. Tuttle erroneously and repeatedly testified that there is "no scientific evidence for migration"; (2) she failed to consider relevant

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[128] (*Id.* at 57 (quoting Int'l Agency for Research on Cancer, World Health Org., 93 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc* (2010) ("IARC 2010 Monograph")) (alteration in original).)

[129] (*Id.* (citing Heller et al., *The Relationship Between Perineal Cosmetic Talc Usage and Ovarian Talc Particle Burden*, Am. J. Obstet Gynecol 1507 (1996) ("Heller 1996")).)

scientific data; and (3) she lacked a basic understanding of biological plausibility concepts.[130] As discussed below, none of these arguments has any merit.

First, plaintiffs contend that Dr. Tuttle's statement that there is "no evidence" supporting plaintiffs' experts' migration hypotheses is in tension with IARC's statement that evidence of migration is "weak."[131] This rhetorical nitpicking ignores the language and reasoning set forth in Dr. Tuttle's report, which state that "Dr. Plunkett's theory of particle migration . . . has not been established in the scientific literature and is ***severely flawed***," and that Dr. Zelikoff's opinions regarding migration are not "***scientifically sound***"[132] – statements that are entirely harmonious with IARC's assessment of the same hypothesis.

Moreover, as Dr. Tuttle explains in her report, the very IARC Monograph cited by plaintiffs makes clear that "animal studies have '*show[n] no evidence of retrograde transport of talc to the ovaries*.'"[133] Further, Dr. Tuttle points out that one of the primary studies relied on by Dr. Plunkett – Heller et al., 1996 – observed talc in ***both*** the ovaries of women who used talc and those who did not, demonstrating that "[t]he presence of talc particles in ovarian tissue plainly is not

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130 (*See* Pls.' Br. at 32-43.)

131 (*Id.* at 41-42.)

132 (Tuttle Rep. at 57, 60 (emphases added).)

133 (*Id.* at 57 (quoting IARC 2010 Monograph) (alteration in original).)

sufficient to indicate migration."[134] Similarly, in criticizing Dr. Zelikoff's opinions related to migration, Dr. Tuttle explains that many of the articles relied upon by Dr. Zelikoff "do not involve talc at all" and that "Dr. Zelikoff could not cite any studies showing that talc particles migrate in the same manner as the particles analyzed in those studies."[135] These examples demonstrate that Dr. Tuttle applied a reliable methodology in reaching her conclusion that plaintiffs' experts' migration theories are "severely flawed" and not "scientifically sound."

Second, plaintiffs also contend that "Dr. Tuttle admitted that she did not read the scientific literature referenced in the IARC monograph on migration or review the relevant body of migration literature to arrive at her opinions on biological plausibility."[136] But Dr. Tuttle made no such admission; to the contrary, she testified that "when reviewing the IARC monograph or any document like it that summarizes a body of science . . . [she] tr[ies] to go to the data that . . . they're reviewing and form[s] [her] own opinions."[137] While plaintiffs take issue with the fact that a handful of studies addressed in the IARC monograph were not listed in Dr. Tuttle's report, that is not a legitimate basis for deeming Dr. Tuttle's opinion about migration unreliable. Indeed, as already discussed, "[n]othing in *Daubert* . . .

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134 (*Id.*)

135 (*Id.* at 60 (citing Zelikoff Dep. 426).)

136 (Pls.' Br. at 42.)

137 (Tuttle Dep. 146:5-9.)

requires an expert to consider every single article on a topic in order to be admitted as an expert." *In re C. R. Bard.*, 2018 WL 4220616, at *5 ("I decline to exclude Dr. Kennelly solely for failing to comment on specific articles in his report."); *see also In re Levaquin*, 2010 WL 8399948, at *10 (if an expert "were not able to discriminate between studies she considered useful and those she did not, she would be required to assess every study of a given topic," which "is not required by *Daubert* or the Rules of Evidence"). Rather, where "the challenging party cite[s] to particular portions of a particular expert's deposition" and invokes "specific studies contrary to his opinion," the expert need only offer a "scientific basis" for not including them in his report. *See In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2187, 2018 WL 4219563, at *3 (S.D. W. Va. Sept. 5, 2018) (this is not a case in which "the challenging party cited to particular portions of a particular expert's deposition testimony where he was asked about specific studies contrary to his opinion and, then, dismissed them in a conclusory manner without a scientific basis").

Dr. Tuttle provided ample "scientific bas[e]s" for not including the handful of studies – which are relegated to a footnote in plaintiffs' brief – in her report. As Dr. Tuttle pointed out, certain of those studies (e.g., the Egli and Newton report, the 2004 Kissler article, the 1979 Venter article and the 2004 Sjosten article) are inapposite in that they either did not examine talc particles or did not involve

perineal application, or both.[138] For example, Dr. Tuttle explained that the Kissler article "appears to be something that examines ***sperm*** transport . . . but nothing about perineal application of talcum powder or talc migration from the external genitalia."[139] Similarly, Dr. Tuttle testified that the Sjosten paper involved ***vaginal*** application of ***starch*** "and not talcum powder."[140] When questioned about the 1979 Venter paper, Dr. Tuttle pointed out that unspecified "chemical substances" had been "deposited in the vagina," which is "different from perineal application."[141] And with respect to the Egli and Newton report, Dr. Tuttle highlighted that it "does not look at talc particles" or "at perineal application."[142] The other articles that Dr. Tuttle does not cite in her report are similarly impertinent and likewise fail to undermine her fundamental critiques of plaintiffs'

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138 (*See, e.g.*, Tuttle Dep. 171:4-13 (explaining that Kissler article "appears to be something that examines ***sperm*** transport . . . but nothing about perineal application of talcum powder or talc particle migration from the external genitalia.") (emphasis added); *id.* 173:9-17 (testifying that the Sjosten paper involved ***vaginal*** application of ***starch*** "and not talcum powder"); *id.* 184:7-14 ("[T]he Egli and Newton report, one, does not look at talc particles; two, does not [look] at perineal application; and three, in this particular statement . . . doesn't look at the ovaries but at the fallopian tubes.").)

139 (*Id.* 171:4-13 (emphasis added).)

140 (*Id.* 173:9-17.)

141 (*Id.* 164:17-165:16.)

142 (*Id.* 184:7-21.)

migration theory.[143] Thus, the smattering of articles highlighted by plaintiffs do ***not*** "support the migration theory of ***perineal*** application of ***talcum powder*** and migration to the ovaries," and there was no reason for them to be included as part of her review.[144] *See also In re C. R. Bard*, 2018 WL 4219563, at *3 (this is not a case in which "the challenging party cited to particular portions of a particular expert's deposition testimony where he was asked about specific studies contrary to his opinion and, then, ***dismissed them in a conclusory manner without a scientific basis***") (emphasis added).

Third, plaintiffs argue that Dr. Tuttle's opinions about biological plausibility amount to *ipse dixit* because she was supposedly unable "to explain why talc may

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[143] (*See, e.g., id.* 163:3-16 (explaining that "the premise of" Henderson 1971 is that "it is ***impossible*** to incriminate talc as a primary cause of carcinomatous changes within either the cervix or the ovary on the preliminary observations described here") (emphasis added); *id.* 168:4-17 (testifying that an isolated statement from the 1986 Henderson paper regarding "[d]irect communication between the external environment and the peritoneal cavity" appears "in the introduction with no citations for it").) Notably, the 2019 McDonald article – which was published after Dr. Tuttle prepared her report – "would not have been available" to review in the first place. (*Id.* 178:15-20.) In any event, as noted in defendants' Biological Plausibility *Daubert* Brief, that article does not support plaintiffs' migration theory either for a variety of reasons, not the least of which is that it was limited to assessing the presence of talc in lymph nodes in the pelvic region and, thus, it provides no evidence that talc moved from the lymphatic system to the ovaries or fallopian tubes. (Defs.' Biological Plausibility Br. at 21 n.44.)

[144] (Tuttle Dep. 184:15-21 ("So I am again . . . not seeing anything based on what I've been able to review for this article that it would support the migration theory of perineal application of talcum powder and migration to the ovaries. So I don't see why I would have found it or cited it in my report.").)

be found in the ovaries if it did not migrate there" and supposedly could not define "retrograde transport," the latter of which plaintiffs argue is "an important medical concept relevant to the migration theory."[145] The former argument misrepresents the record. As just discussed, Dr. Tuttle fully explains why the mere presence of talc particles in ovarian tissue is not sufficient to indicate migration given that the Heller study – which plaintiffs and their experts heavily rely on – found that "'*talc particles were observed to a similar extent with both and unexposed subjects*.'"[146] Although Dr. Tuttle testified that "others involved in this litigation get more in detail" about the presence of talc in ovarian tissue, she reiterated that her role was to address the issue "through the lens of the Hill criteria."[147] This in no way

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145 (Pls.' Br. at 42-43.)

146 (Tuttle Rep. at 57 (quoting Heller 1996).) Plaintiffs' argument is especially disingenuous because it cites to a portion of the deposition where Dr. Tuttle was explaining that the mere presence of talc in ovarian tissue did not establish migration – and it was ***plaintiffs' counsel*** who asked her to answer the question without referring to migration. (Tuttle Dep. 209:12-17 ("This is a different question, though. I'm not asking you about the migration at this moment. I'm asking you specifically, based on your review of the scientific evidence and literature, has talc been found in the ovaries of women?"); *see* Pls.' Br. at 42 n.137 (citing Dr. Tuttle's answer to this question as supposed support for their claim that she could not explain why talc may be found in the ovaries if it did not migrate there).)

147 (Tuttle Dep. 211:9-14.)

undermines her opinions; if anything, it reflects that Dr. Tuttle (in contrast to plaintiffs' experts) sought to cabin her opinions to her relevant expertise.[148]

While plaintiffs also claim that Dr. Tuttle's testimony regarding "retrograde transport" somehow undermines the reliability of her opinions, their argument fundamentally mischaracterizes Dr. Tuttle's deposition testimony. When asked whether the reference to "retrograde movement" in the IARC statement quoted on page 57 of Dr. Tuttle's report is "synonymous with the issue of migration" they were addressing during the deposition, Dr. Tuttle responded that it was "referring to several different studies."[149] As Dr. Tuttle further explained, "in order to discuss . . . retrograde movement as stated [in that discussion], [she] would need to

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[148] Notably, Dr. Tuttle similarly resisted plaintiffs' counsel's invitation to weigh in on "cytotoxicity" – a concept that is not discussed at all in Dr. Tuttle's report. (*See generally* Tuttle Rep.) Plaintiffs emphasize that Dr. Tuttle was unable to define the concept "very clearly and scientifically" (Pls.' Br. at 34 (quoting Tuttle Dep. 339:9-11)); however, she explained that the concept is outside the scope of her opinions in this litigation and does not have any bearing on her opinions (Tuttle Dep. 339:17-19). Plaintiffs also contend that Dr. Tuttle was unable to address whether the ovaries or the respiratory system have the ability to clear foreign particles notwithstanding that "the body's defense mechanisms are included in her report." (Pls.' Br. at 36 (citing Tuttle Rep. at 33).) But the page cited by plaintiffs simply summarizes the observational studies that have examined the potential exposure to asbestos fibers from the use of talcum products. (*See* Tuttle Rep. at 33.) Dr. Tuttle's discussion focuses on the literature and does not specifically delve into the body's defense mechanisms – much less those specifically probed by plaintiffs' counsel during Dr. Tuttle's deposition.

[149] (Tuttle Dep. 149:15-20.)

go back and look at their references and look at the studies that they are citing."[150] Indeed, it is precisely because the IARC discussion did not specify whether the studies it was summarizing specifically addressed "perineal application" or some other application that Dr. Tuttle did not want to offer a "specific definition."[151]

2. Dr. Tuttle's Opinions On Inflammation And Carcinogenesis Are Reliable.

Dr. Tuttle followed a similarly sound approach in addressing ***plaintiffs*** experts' theory of inflammation and carcinogenesis – i.e., "whether talc causes inflammation or whether inflammation is itself related to the initiation of ovarian cancer."[152] Specifically, Dr. Tuttle reviewed the scientific literature corresponding to that theory, including: (1) the Hamilton study, in which no inflammation was observed upon injecting the ovaries of female rats with talc; (2) scientific studies that have shown that anti-inflammatory drugs do not reduce the risk of ovarian cancer; and (3) studies, including the Merritt study, finding no statistically significant relationship between a history of pelvic inflammatory disease and any type of ovarian cancer.[153] Based on this review of the scientific literature, Dr. Tuttle concludes in her report that "the notion that either talc causes inflammation

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150 (*Id.* 151:12-16.)

151 (*Id.* 151:22-152:6.)

152 (Tuttle Rep. at 27.)

153 (*Id.*)

or that inflammation causes or promotes ovarian cancer remains unsupported."[154] She also criticizes Dr. Zelikoff's opinion that talcum powder products cause an inflammatory tissue reaction along these very lines.[155] In short, as with Dr. Tuttle's opinions about migration, these opinions are "essentially, critiques of [p]laintiffs' experts' evidence, methodologies, and conclusions," which is "entirely appropriate" under Rule 702. *In re Abilify*, 299 F. Supp. 3d at 1368; *see also In re Mirena*, 169 F. Supp. 3d at 418-19 ("[G]iven that [d]efendants' experts are attempting to prove a negative—that secondary perforation does not exist—pointing to the absence of convincing studies or the weaknesses of studies on which [p]laintiffs rely, and evaluating them in light of their clinical experience, training and research, is in these circumstances a logical and valid approach.").

In their motion, plaintiffs nonetheless argue that these opinions are improper "*ipse dixit*" opinions because Dr. Tuttle "failed to consider important scientific evidence on inflammation and carcinogenesis" and "exhibited a wholly deficient understanding of relevant inflammatory processes[.]"[156] Plaintiffs' argument focuses on a 2014 FDA letter postulating on the plausibility of perineal talc reaching the fallopian tubes and eliciting an inflammatory response and a 2014

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154 (*Id.*)

155 (*Id.* at 61.)

156 (Pls.' Br. at 44.)

article written by Dr. Tuttle that "touche[s]" on the subject of inflammation.[157] According to plaintiffs, "[w]hen asked if the FDA description is similar to the type of foreign body reaction and inflammatory response in her article, Dr. Tuttle had absolutely no idea."[158] But as Dr. Tuttle explained, the FDA letter – which is bereft of any references – addresses "the ovaries and other avenues of the female reproductive system," whereas the 2014 article she wrote touches on the "inflammatory process" "very generally" and does so in connection with the lung, an entirely different organ.[159] Although Dr. Tuttle "addresse[s] inflammation briefly in [her] report," that discussion is based on the scientific literature and does ***not*** require that Dr. Tuttle "compare[] all the organs of the body and their various defense mechanisms."[160] Indeed, such a granular exercise would have been

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157 (*Id.* at 43-44.) Plaintiffs also reference a couple of articles that Dr. Tuttle did not cite in her report that supposedly undermine the reliability of her inflammation opinions. (*See id.* at 44 n.143 (noting that Tuttle "did not consider Shukla et al. 2009 or Buz'zard et al. 2007").) However, as already discussed, Shukla addresses gene expression – which does not by itself say anything about the ostensible carcinogenicity of talc – and focuses largely on mesothelial cells and asbestos. And as explained in the J&J defendants' Biological Plausibility *Daubert* Brief, the Buz'Zard article tested an immortalized granulosa cell line that is only possibly relevant to sex cord-stromal tumors (which can arise from granulosa tissues, and which several plaintiffs' experts do not even allege can be caused by talc). (Defs.' Biological Plausibility Br. at 16.) And the "normal" ovarian cells tested were not actually normal, but were instead "immortalized" by some undocumented method that could affect the reaction observed. (*Id.*)

158 (Pls.' Br. at 44.)

159 (Tuttle Dep. 327:10-19, 329:15-21.)

160 (*Id.* 315:15-21, 329:21-330:1.)

needless given that there "there are others who get more into the mechanisms and pathways regarding inflammation that [she] do[es]."[161] In short, as with Dr. Tuttle's opinions regarding migration, Dr. Tuttle's opinions on inflammation and carcinogenesis are based on her fair and reliable review of the scientific literature.

For all of these reasons, plaintiffs' challenges to the biological plausibility opinions offered by Dr. Tuttle are meritless, and none of her opinions should be excluded under *Daubert*.

III. DR. MOORE'S OPINIONS SHOULD NOT BE EXCLUDED.

Plaintiffs finally argue that Dr. Moore lacks the requisite expertise to critique experts in fields other than toxicology; that she is unqualified to offer opinions about the presence of fibrous talc in the talcum powder products; and that her supposed "cherry-picking" of the literature somehow renders all of her opinions unreliable.[162] Each of these arguments should be rejected.

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161 (*Id.* 315:15-21, 319:18-20.) The same rationale disposes of plaintiffs' complaint that Dr. Tuttle was unable to "answer basic questions regarding whether [reactive oxygen species] are significant to the carcinogenic process." (Pls.' Br. at 35.) Indeed, when asked if reactive oxygen species are significant to the carcinogenic process, Dr. Tuttle responded that "[i]t would depend" and that she had "not done a specific assessment of that in this case" (Tuttle Dep. 324:13-19), which is a far cry from not being able to answer basic questions regarding the concept.

162 (*See* Pls.' Br. at 45-53.)

A. Dr. Moore Is More Than Qualified To Offer Her Opinions.

Plaintiffs do not challenge Dr. Moore's qualifications to offer the vast majority of opinions set forth in her report; instead, they argue that Dr. Moore's experience as a toxicologist does not suffice for purposes of critiquing plaintiffs' experts, Dr. Saed and Dr. Longo, and opining on the narrow issue of fibrous talc.[163] As explained below, plaintiffs' arguments distort the scope of Dr. Moore's opinions.

First, while plaintiffs are correct that Dr. Moore is not "a cancer researcher" and has not "published in the areas of inflammation and ovarian cancer," her criticisms of Dr. Saed do not relate to cancer biology; rather, they relate to fundamental principles of laboratory experiments, which she is more than qualified to offer. Specifically, Dr. Moore opines that "[d]eficiencies regarding the methodological study design employed by Dr. Saed make his results scientifically unreliable" because, *inter alia*, (1) he "failed to validate the assays used in his manuscript"; (2) "Dr. Saed's experiment plated and treated all cells at one time" such that his "experiment included only one biological replicate"; and (3) Dr. Saed provided "uncertain and conflicting testimony and documentation concerning the amount of DMSO used in his control dishes."[164] These critiques are grounded in

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163 (*See id.* at 45-47.)

164 (Moore Rep. at 93-95.)

Dr. Moore's extensive experience as a scientist and easily satisfy the requirements set by the Third Circuit.

With respect to Dr. Longo's analysis, Dr. Moore does not address his various (unreliable) methods for testing talc products for asbestos. Rather, she criticizes his claim that consumers who have used the Products have been exposed to "***significant*** *airborne levels of amphibole asbestos*"[165] because the amount of asbestos he claims to have identified does not support this statement. As Dr. Moore explains, "[i]n non-statistical terms, the word 'significant' is an adjective with multiple potential definitions" and Dr. Longo failed to explain why he considered the purported fiber exposure "meaningful or important."[166] As she explains in her report, Dr. Moore calculated an actual estimation of anticipated dose by converting Longo's bulk measurements to airborne concentrations and then comparing the results to known acceptable levels.[167] This is precisely within her area of expertise because the core of what toxicologists do is to analyze dose in making risk assessments; indeed, as Dr. Moore explains in her report, it "is the most fundamental and pervasive concept in toxicology."[168]

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165 (*Id.* at 44.)

166 (*Id.* at 44-45.)

167 (*Id.* at 45-48.)

168 (*Id.* at 8.)

Second, plaintiffs also argue that Dr. Moore is not qualified to opine on the presence of fibrous talc particles within the Products, but Dr. Moore does not offer any such opinions, rendering this argument moot. To the extent Dr. Moore addressed fibrous talc at her deposition, it was in response to plaintiffs' questioning and demonstrated that Dr. Moore is sufficiently familiar with the concept to answer questions about it if asked.[169]

B. Dr. Moore's Opinions Are Reliable.

Plaintiffs also argue that Dr. Moore's opinion that the "[s]cientific literature does not support a causal relationship between perineal talc use and ovarian cancer"[170] is based on an unreliable methodology because "she only considered evidence that supports her litigation report."[171] This argument, which only attacks small portions of Dr. Moore's opinions, lacks merit.

First, plaintiffs argue that the absence of any reference to the previously discussed 2018 Health Canada Draft Screening Assessment that supposedly "contradict[s] Dr. Moore's finding" somehow demonstrates that Dr. Moore has "'cherry-pick[ed]'" the relevant scientific data.[172] As already discussed, however, "[n]othing in *Daubert* . . . requires an expert to consider every single article on a

169 (Moore Dep. 284:15-16 (Q. "Do you know what fibrous talc is?" A. "I do.").)

170 (Pls.' Br. at 49 (alteration in original) (citing Moore Rep. at 1).)

171 (*Id.*)

172 (*Id.* at 51.)

topic in order to be admitted as an expert." *In re C. R. Bard*, 2018 WL 4220616, at *5 ("I decline to exclude Dr. Kennelly solely for failing to comment on specific articles in his report."); *see also In re Depakote*, No. 14-CV-847-NJR-SCW, 2015 WL 4775868, at *4 (S.D. Ill. Feb. 13, 2015) ("Here, we have Dr. Blume's selective choice of *articles* and *studies*, to which she is entitled to give different weight based on design of the study, the quality of the study, the authors of the article, etc."). This is all the more true because the 2018 Health Canada document is not even a scientific article. Rather, as Dr. Moore explained, it is a "draft" "screening assessment" produced by regulators in another country.[173] And far from reaching a definitive conclusion on causation, it merely states that the body of talc literature supports classifying talc use as a "***potential*** concern for human health."[174] Needless to say, plaintiffs do not cite any authority for the absurd proposition that an expert's opinions should be excluded for failure to cite a draft precautionary regulatory assessment. To the contrary, both of their cases involved the same plaintiffs'-side expert statistician (Dr. Nicholas Jewell) whose opinions on

[173] (Moore Dep. 173:18-23.) As Dr. Moore noted, it is "unclear what the final assessment will say." (*Id.* 173:23-24.)

[174] Health Canada, Draft Screening Assessment: Talc ($Mg_3H_2(SiO_3)_4$) (Chem. Abstracts Serv. Registry No. 14807-96-6) at 28 (2018) (attached as Ex. A58 to Tersigni Cert.) (emphasis added).

causation in unrelated litigation were unreliable on ***multiple*** levels,[175] including that they were the product of pervasive and egregious cherry-picking of data. For example, in *In re Zoloft*, the Third Circuit affirmed the exclusion of Dr. Jewell's causation opinion because, *inter alia*, he "selectively emphasize[d] observed consistency . . . only when the consistent studies support[ted] his opinion." 858 F.3d at 797 (citation omitted). In particular, he highlighted the "insignificance of results reporting odds ratios below 1 but not the insignificance of those reporting odds ratios above" and "also paid attention to the upper bounds of the confidence intervals associated with odds ratios below 1, but not to the lower bounds." *Id.*

Similarly, in *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Products Liability Litigation v. Pfizer, Inc.*, 892 F.3d 624 (4th Cir. 2018), Dr. Jewell's initial statistical calculations "showed a statistically insignificant association between Lipitor and the onset of diabetes, yielding a p-value of .0654." *Id.* at 634. However, Dr. Jewell omitted that finding from his initial expert report and instead reported the results using a mid-p value, yielding a statistically significant result of p=.04. *Id.* The Fourth Circuit explained that "Dr. Jewell's

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[175] One of those grounds was that Dr. Jewell "unreliably analyzed the trend in ***insignificant*** results," *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 797 (3d Cir. 2017) (emphasis added) – which squarely undermines plaintiffs' earlier statistical significance arguments in connection with Dr. Mossman's opinions. *See also id.* at 799 ("While an insignificant result *may* be consistent with a causal effect, Dr. Jewell's discussion is too far-reaching, sometimes understating the importance of statistical significance.").

choice to include in his report the results of some tests he performed (which supported the plaintiffs' argument) but exclude the results of another (which did not) . . . lacked the hallmark of science properly performed." *Id.* at 634-35. Based on this selective approach to Dr. Jewell's ***own*** calculations – as well as numerous "other issues with Dr. Jewell's process" – the Court of Appeals affirmed the exclusion of his opinions.

Here, by contrast, Dr. Moore's report – which contains hundreds of references in more than 450 footnotes substantiating her opinions – addresses the totality of the scientific literature, examining ***both*** the case-control studies that are the lynchpin of plaintiffs' experts' opinions and the cohort studies that support a finding of no causal association between perineal application of talcum powder and ovarian cancer.[176] Indeed, Dr. Moore has an entire table devoted to the case-control studies, describing their key features, including the population, number of cases and controls, exposure category, odds ratio, whether the results were statistically significant and whether there was a finding of a dose-based response.[177] This fulsome analysis is not remotely comparable to the methodologies deemed unreliable in plaintiffs' cases, which involved multiple deficiencies, including some that support exclusion of ***plaintiffs'*** experts.

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176 (Moore Rep. at 20-25, 30-31.)

177 (*Id.* at 22-24.)

Second, plaintiffs also appear to suggest that Dr. Moore's criticisms of the inflammation opinions espoused by plaintiffs' experts are unreliable because she failed to consider the Shukla study "upon which the plaintiffs' experts relied for their opinion that talcum powder induces inflammation and causes biologic changes consistent with carcinogenicity."[178] But as discussed in Section I.B, above, the Shukla study does not support plaintiffs' theory of causation. Moreover, if plaintiffs thought it had any bearing on Dr. Moore's opinions, they should have asked her about it at her deposition – but they did not. *See In re C. R. Bard*, 2018 WL 4219563, at *3 ("I decline to exclude Dr. Giudice solely for failing to comment on specific articles never presented to him for comment"; further noting that "nothing in *Daubert* requires an expert to consider every single article on a topic in order to be admitted as an expert").

In sum, plaintiffs' limited qualifications and reliability arguments do not even attempt to challenge the vast majority of Dr. Moore's opinions in her voluminous report. And to the extent plaintiffs have attempted to challenge certain portions of Dr. Moore's report, their arguments are unavailing and should be rejected.

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[178] (Pls.' Br. at 53.)

CONCLUSION

For the foregoing reasons, the J&J defendants respectfully request that the Court deny plaintiffs' motion to exclude the opinions of defendants' experts Brooke T. Mossman, M.S., Ph.D.; Kelly S. Tuttle, Ph.D.; and H. Nadia Moore, Ph.D.

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Respectfully submitted,

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